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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,266	07/11/2001	Olivier de Lacharriere	016800-454	8334

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/902,266	De LACHARRIERE et al.
Examiner	**Art Unit**
Michele Flood	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 7, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above, claim(s) *17* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-16 and 18-47* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendments filed on April 7, 2003. Acknowledgment is made of newly submitted Claims 18-47.

Response to Arguments

Election/Restriction

Applicant submits that "where product and process claims are presented in the same application, in the case of an elected product, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all of the limitations an allowed product claim." Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), process claims which depend from or otherwise include all of the limitations of the allowable product will be rejoined and fully examined for patentablility under 37 CFR 1.104, at the time a product claim is found allowable. However, no product claim has been found allowable, in the instant case. Thus, the finality of the restriction requirement set forth in the previous Office action remains FINAL.

This application contains claim 17 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action. (37 CFR 1.144). See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 11, 14-16 and 19-47 as amended remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Drug Launches (U). The rejection stands for the reasons set forth in the previous office action and set forth below.

Applicant argues that Drug Launches fails to anticipate the claimed invention. However, this is unpersuasive because Drug Launches teaches OCUVITE™, which comprises zinc oxide (40 mg), copper oxide (2 mg), vitamin C (60 mg), vitamin E (30 IU or 30 mg), vitamin A (as beta-carotene, 5000 IU or 3 mg), and selenium (40 mcg). The active ingredients are combined with a pharmaceutically acceptable carrier in the making of tabs for oral administration. Applicant argues that the amounts of the referenced composition are neither disclosed nor suggested as being effective to promote hair regrowth and/or retard hair loss, increase the mean diameter of strands of hair, increase hair density, improve the quality and/or the appearance of a head of hair or to induce repigmentation of the hair. Although, the reference does not expressly teach that the composition can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is

inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Applicant further argues that the Bausch & Lomb facsimile relied on in support of the 102 rejection reveals that the amounts of the ingredients disclosed in the referenced composition do not represent the actual amounts of ingredients present in the composition itself but rather Label/Claim amounts. Thus, Applicant concludes that the amounts of the disclosed ingredients in the referenced composition are outside the limits of the claimed composition. However, Applicant's arguments are neither persuasive nor commensurate in scope to the limitations of the claimed invention because the amounts of the relevant ingredients comprising the OCUVITE® still comprise the same amounts of the same ingredients, as instantly claimed by Applicant. For instance, while the relied upon facsimile may disclose different amounts of the ingredients comprising a tablet, the actual amounts of the batch composition are one and the same as claimed by Applicant. Thus, with regard to the newly and instantly claimed claims directed to compositions comprising the claimed amounts of the only and same active ingredients as taught by the cited reference, the Office notes that whether formulated as a tablet, as a topical anti-hair loss composition or formulated for oral administration, the composition taught by Drug Launches still comprises the same ingredients having the same amounts of the same ingredients, as instantly

claimed by Applicant. Moreover, there is nothing in the cited reference to preclude the use of the referenced composition as any of the claim-designated formulations.

Hence, the cited reference is deemed to anticipate the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7, 8 and 10-13 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kronnie (A1) in view of Cauwenbergh (A), Proctor (B) and Nishida et al. (N, JPO translation provided attached hereto). The rejection stands for the reasons set forth in the previous office action and set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5

USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary reference of Kronnie was used because Kronnie teaches a topical composition comprising vitamin A acetate, vitamin E acetate, vitamin C, zinc, and iron phosphate to stimulate the regrowth of hair. The composition taught by Kronnie was effective in promoting hair growth in previously bald people and in people having hair loss. Because Kronnie does not teach a composition comprising selenium, further comprising the ingredients of Claim 12 (i.e., antioxidant, catalase, peroxidase, a synthetic molecule, a sulfur-containing amino acid), and the instantly claimed dose amounts of vitamin A, vitamin C, vitamin E, zinc and selenium, the secondary references of Cauwenbergh, Proctor and Nishida were used because each teaches that at the time the invention was made the instantly claimed ingredients were known in the art to have the functional effect for promoting hair regrowth and/or retard hair loss.

Thus, with Kronnie providing the motivation to use a composition comprising vitamin A acetate, vitamin E acetate, vitamin C, zinc, and iron phosphate to stimulate the regrowth of hair, and with Cauwenbergh teaching selenium sulfide as an anagen hair-inducing agent that reduces the shedding of hair and increases the diameter of a hair shaft and zinc pyrithione as a hair shedding reductant, also; and with Proctor teaching that compositions comprising either ascorbates (a vitamin C salt) or sulfhydryls such as the sulfur-containing amino acids cysteine, N-acetylcysteine, glutathione, etc., which stimulate hair growth, increase the rate of hair growth, increase hair diameter, follicular neogenesis, and inhibit hair loss; and with Nishida teaching hair growth tonic comprising effective dose amounts of carotenes, which is additionally formulated

with effective amounts of 1-hydroxy-2-pyridone and a plant extract having anti-inflammatory, blood circulation-promoting and/or 5 and alpha; -reductase-inhibitory activity, and further teaching that the referenced composition can be blended with other cell activation components such as vitamin A, ascorbic acids (vitamin C), and tocopherols (vitamin E), it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed old and well-known ingredients to provide the claimed invention as suggested by the cited references. As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference. Furthermore, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the amounts of the ingredients used in the claimed composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to select result-effect amounts of the claimed ingredients to provide a composition with the claimed functional effect for promoting hair regrowth and/or retarding hair loss. Hence, the claimed invention is no more than the routine optimization of a result effect variable. Therefore, the invention as a whole was clearly prima facie obvious in the absence to the contrary.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

June 15, 2003

CHRISTOPHER R. TATE
PRIMARY EXAMINER